FEB.16.2007 12:00PM

RECEIVED CENTRAL FAX CENTER

FEB 1 6 2007

GY0111NP USSN 10/787,284 Page 7 of 10

REMARKS

Reconsideration and allowance of the above-identified patent application are respectfully requested in view of the above amendments and remarks that follow.

The claims have been amended to more clearly define the invention. More specifically, claim 1 has been amended to refer to the term "2',3'dideoxyinosine" instead of "didanosine" and to recite in step (a) that the enzyme is a human adenosine deaminase enzyme. This amendment is supported by claim 7 which is now cancelled. Claims 8, 9 and 10 have been amended to delete the phrase "or conservative variations thereof." Claim 20 has been amended to delete the first occurrence of the word "and."

New claims 22-25 have been added. New claim 22 recites a method of making ddI comprising (a) contacting a human adenosine deaminase enzyme (ADA) immobilized onto an insoluble support with a dideoxyadenosine (ddA) solution of at least about 1% weight volume ddA in water for a time and under conditions to produce a ddI solution; and (b) isolating the ddI from the ddI solution. Claim 22 is supported by original claims 1 and 7. New claim 23 and 24 depend from claim 22 and are supported by claims 8 and 9, respectively. New claim 25 corresponds to claim 23 and further recites that the insoluble support is a solid resin material having a diameter of 250 to 600 microns (supported on page 14, lines 26-27 of the specification). New claim 26 recites specific support materials (supported on page 14, lines 27-29 of the specification).

The specification has been amended on page 4 in the Summary of the Invention to make reference to the term "2,3'-dideoxyinosine" instead of "didanosine." The reference to "4%" weight volume ddA was amended to read "1%" for consistency with claim 1.

Claims 1-2, 17-18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

GY0111NP USSN 10/787,284 Page 8 of 10

In view of the amendments to the claims described above, it is submitted that rejections under 35 U.S.C. 112, second paragraph, have been obviated.

Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as filing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In view of the amendments made to claims 8-10, it is submitted that the rejection under 35 U.S.C. 112, first paragraph, has been obviated.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farina, et al. (AC). Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dessouki, et al. (AG) in view of Farina, et al. (AC).

It is noted that the above rejections were not made with respect to claim 7. Claim 1 has been amended to recite the features of claim 7; i.e., that the enzyme is a human adenosine deaminase. Thus, it is submitted that the rejections have been obviated by the amendment to claim 1.

Claims 1-8 and 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dessouki, et al. (AG) in view of Farina, et al. (AC) and further in view of either Daddona, et al. (U) or Wiginton, et al. (V).

It is the Examiner's position that:

The first two references have been characterized supra. Daddona, et al. and Wiginton, et al. teach the sequence of human adenosine dearninase (ADA) as SEQ ID NO:1. It would have been obvious to one of ordinary skill in the art to use the ADA taught by Daddona, et al. or Wiginton, et al. in the method of the instant claims, absent unexpected results.

The Patent and Trademark Office has not pointed to any specific disclosure by either Daddona, et al., or Wiginton, et al., that discloses or suggests using ADA immobilized on an

GY0111NP USSN 10/787,284 Page 9 of 10

insoluble support for converting ddA to ddI. Moreover, it is respectfully submitted that the Patent and Trademark Office has failed to show any disclosure or suggestion in the references to combine them in a manner that would arrive at applicants' presently claimed invention. Accordingly, it is requested that the rejection be withdrawn.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dessouki, et al. (AG) in view of Farina, et al. (AC), further in view of either of Daddona, et al. (U) or Wiginton, et al. (V) and further in view of Wada, et al. (3AC).

It is the Examiner's position that

The first four references have been characterized *supra*. Wada, et al. teach the preferred codons in different organisms. It would have been obvious to use the teachings of Wada, et al. as to the preferred codons in *E. coli* to change the coding sequence for ADA to those codons, absent unexpected results.

In order to support this rejection, the Patent and Trademark Office has relied on five references. However, no sound basis has been proffered to explain how one of ordinary skill in the art would be motivated to combine the five references in a manner that would arrive at applicants' invention. Accordingly, it is respectfully requested that the rejection be withdrawn.

New claims 23-26 are submitted to be patentable for the same reasons as described above with respect to claims 1-22. Additionally, the cited references fail to disclose or suggest the use of the solid resin material having a diameter of 250-600 microns; e.g., IPS-400, let alone the unexpected results noted by the Examiner in Table 2 of the specification.

It is believed that the application is now in condition for allowance. An early and favorable Office Action is courteously solicited.

GY0111NP USSN 10/787,284 Page 10 of 10

The application now contains three independent claims and a total of 25 claims. The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. 1.17 which may be required, or credit any overpayment, to Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,

Noven KNAll

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000

Warren Volles Attorney for Applicant

Reg. No. 33,810

Phone: 203-677-6997 Date: February 16, 2007